Exhibit “5”

PSA – FDA Bans Doctors Medical Powdered Gloves

12 min read

The US Food and Drug Administration (FDA) has finalized a rule banning the use of powdered gloves in medicine because they pose dangers to human health.

The ban, **first proposed** in March 2016, will further propel efforts already underway to phase out the use of prepowdered surgeons' gloves, powdered exam gloves, and absorbable powder for lubricating surgeons' gloves. Professional societies have advocated for a ban, and many large health systems have already either restricted or completely ended the use of such products, as have a majority of individual clinicians.

"While medical gloves play a significant role in protecting patients, healthcare providers, and other individuals in close proximity, powdered gloves are very dangerous for a variety of reasons," the FDA said in a statement.

Powder used within all types of gloves has been associated with many potentially serious adverse events, including severe airway inflammation, hypersensitivity reactions, allergic reactions (including asthma), lung inflammation and damage, granulomas, and peritoneal adhesions.

Respiratory allergic reactions can also result from proteins in aerosolized glove powder, the FDA notes.

According to the agency, nonpowdered alternatives to both surgeons' and patient examination gloves are available that provide similar protection, dexterity, and performance but without any of the risks associated with powdered gloves. "Thus, a transition to alternatives in the marketplace should not result in any detriment to public health."

Most device removals from the US market are initiated by manufacturers, not the FDA. In fact, this is only the second time the FDA has ever **done so**. The first was the removal of prosthetic hair fibers in 1983. The FDA has now proposed **one other ban,** on the use of electrical stimulation devices to treat self-injurious or aggressive behavior.

Source: ***http://www.medscape.com/viewarticle/873394***

What Is An FDA Medical Device Bans

What is a Medical Device Ban?

A medical device ban is a total prohibition on the current and future sales, distribution, and manufacturing of a medical device.

The FDA has the authority to ban a medical device intended for human use if it finds, on the basis of all available data and information, that the device presents a substantial deception to patients or users about the benefits of the device, or an unreasonable and substantial risk of illness or injury, which cannot be corrected by a change in the labeling. (see Section 516(a) of the Federal Food, Drug and Cosmetic Act; 21 CFR 895.20)

How Often Does the FDA use this Authority to Protect Public Health?

The FDA very rarely acts on this authority. Until 2016, the FDA banned only one other medical device, prosthetic hair fibers. The FDA found there was no public health benefit to this device. This device presented a substantial deception to patients or users about the benefits of the device. The prosthetic hair fibers did not stimulate hair growth nor conceal baldness, but could actually cause serious infections, illness, and injuries from their implantation. We believed that the labeling and advertising materials directly or implied misrepresented the device as safe, effective, and causing little or no discomfort, among other misleading claims.

On December 19, 2016, the FDA published a final rule banning powdered gloves based on the unreasonable and substantial risk of illness or injury to individuals exposed to the powdered gloves. The risks to both patients and health care providers when internal body tissue is exposed to the powder include severe airway inflammation and hypersensitivity reactions. Powder particles may also trigger the body's immune response, causing tissue to form around the particles (granulomas) or scar tissue formation (adhesions) which can lead to surgical complications.

For a detailed description of the risks that the FDA identified, please refer to the final rule. There are other surgical and patient examination gloves available that provide the same level of protection, dexterity, and

performance without posing the same risks to patients and health care providers.

The final ban is effective for powdered surgeon's gloves, powdered patient examination gloves, and absorbable powder for lubricating a surgeon's glove that are already in commercial distribution and for these devices that are already sold to the ultimate user, such as small medical practices and hospitals, on January 18, 2017.

In April 2016, the FDA proposed a ban on electrical stimulation devices (ESDs), intended to reduce aggressive or self-injurious behaviors, because they present an unreasonable and substantial risk of illness or injury to the public. ESDs administer electrical shocks through electrodes attached to the skin of individuals to attempt to condition them to stop engaging in self-injurious or aggressive behaviors. Many people getting exposed to these devices have intellectual or developmental disabilities that make it difficult to communicate their pain or consent. A number of significant psychological and physical risks associated with the use of these devices, including depression, anxiety, worsening of self-injury behaviors and symptoms of posttraumatic stress disorder, pain, burns, and tissue damage. In addition, there is a risk of errant shocks from a device malfunction. As these risks cannot be eliminated through new or updated labeling, banning the product is necessary to protect public health. The proposed ban does not apply to ESDs used to create aversions to other conditions or habits, such as smoking. For a detailed description of the risks that the FDA identified, please refer to the proposed rule.

What Process Does the FDA Follow to Ban a Medical Device?

The FDA makes the determination to ban a device by analyzing and weighing the risks and benefits the device poses to individuals. This analysis may include:

- Identifying and studying the device, including assessing adverse events,
- Analyzing the risks and benefits posed by alternative devices and treatments being used in current medical practice,
- Analyzing whether a change in labeling on the device mitigates the risk,

- Evaluating the medical literature,
- Conducting a panel meeting with outside experts,
- Discussing concerns with professional societies, and
- Reviewing information from health care professionals and patients.

The FDA can ban a device without actual proof of illness or injury, and only needs to find that a device has the potential to present the required degree of risk based on all available data and information.

The FDA may initiate proceedings to ban the device if:

- the device presents substantial deception in the labeling or an unreasonable and substantial risk of illness or injury, and
- such deception or risk cannot be, or has not been, corrected or eliminated by labeling or a change in labeling.

If the FDA decides to initiate proceedings to ban a device, a notice of proposed rulemaking is published in the Federal Register.

Source: **https://www.fda.gov/MedicalDevices/Safety/MedicalDeviceBans/default.htm**

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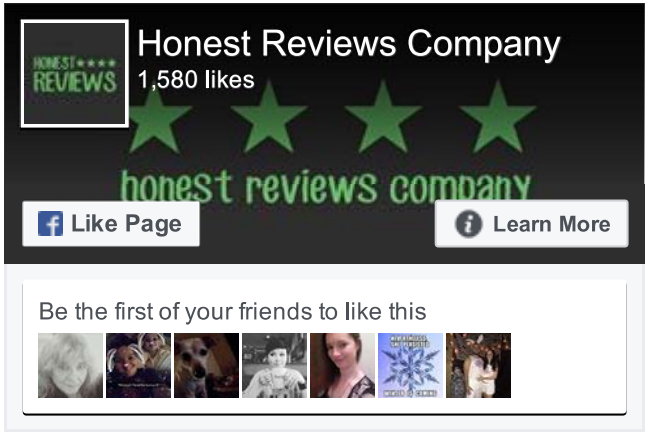

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